

Committee on Ways and Means

Drug Reimportation Is Unaffected by the U.S.-Australia FTA

- The Australia FTA does not prevent Congress from passing legislation on drug reimportation. Under the U.S. Constitution no trade agreement could do this.
- Any law passed by Congress will always trump the FTA.
- There is nothing in the Australia FTA or H.R. 4759 that changes U.S. patent law or the Federal Food, Drug, and Cosmetic Act (FDCA).
- The patent provision in the FTA restates U.S. law and applies to all patents, not just pharmaceuticals. Not including this provision would be devastating to U.S. intellectual property rights holders in every sector.
- Australian law already bans the exportation of drugs dispensed under its Pharmaceutical Benefits Scheme (PBS).
- Unlike Canada, Australian law explicitly prohibits other parties, such as a wholesaler or pharmacist, from exporting non-PBS dispensed drugs.
- Therefore, any change in U.S. law would have no practical effect on reimportation from Australia due to Australian domestic law (regardless of the FTA) and therefore Australia would have no plausible basis to claim harm or pursue sanctions.